MAYO CLINIC LABORATORIES

NEW TEST

Notification Date: August 12, 2025
Effective Date: September 23, 2025

Hepatitis D Virus RNA Detection and Quantification, Real-Time RT-PCR, Serum

Test ID: HDVQU

Useful for:
Detection of hepatitis D virus (HDV) for diagnosis of acute or chronic hepatitis D

Determine HDV RNA level in serum to monitor progression and response to antiviral therapy for chronic hepatitis D

Methods:
Real-Time, Reverse Transcription-Polymerase Chain Reaction (RT-PCR)

Reference Values:
Undetected

Specimen Requirements:

Supplies:	Sarstedt Aliquot Tube, 5 mL (T914)
Collection Container/Tube:	Serum gel
Submission Container/Tube:	Plastic vial
Specimen Volume:	2.2 mL
Collection Instructions:	1. Centrifuge blood collection tube per collection tube manufacturer's instructions (eg, centrifuge within 2 hours of collection for BD Vacutainer tubes). 2. Aliquot serum into plastic vial.
Minimum Volume:	1.0 mL

Specimen Stability Information:

Specimen Type	Temperature	Time	Special Container
Serum SST	Frozen (preferred)	35 days	Aliquot Tube
	Refrigerated	5 days	Aliquot Tube

Cautions:

This assay is optimized for the detection and quantification of hepatitis D virus (HDV) genotypes 1 to 8, but due to unexpected mismatches between the polymerase chain reaction assay primers and unusual or rare HDV target sequences, some serum specimens may yield "Undetected" results despite the presence of HDV RNA. Therefore, results should be interpreted with caution, considering the patient's risk factors for HDV infection, the analytical sensitivity of the assay, and possible geographic origin of the infecting HDV strain. Follow-up HDV RNA testing is recommended for patients with initially "Undetected" HDV RNA test results but at high risk for or suspected to have chronic hepatitis D.

In immunocompetent individuals, undetectable HDV RNA results indicate only the absence of HDV RNA in the serum specimen tested but do not exclude the diagnosis of HDV infection, given the relatively short duration of viremia (2 to 8 weeks after infection) in these individuals. Immunocompetent individuals with HDV infection would be expected to have repeatedly positive HDV-specific IgG and total antibody test results.

Heparinized or visibly lipemic serum specimens may result in reduced assay sensitivity, with possible false-negative or under-quantified HDV RNA test results.

Due to differences in design and analytical performance for different assays detecting and quantifying HDV RNA in human serum, serial testing of HDV viral load in a given patient over time should be performed using the same molecular assay.

CPT Code:

87523

Day(s) Performed: Varies (once per week) **Report Available:** 1 to 10 days

Questions

Contact James Conn, Laboratory Resource Coordinator at 800-533-1710.